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PATENT
Atty. Docket No.: 019633-000128US

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By: 
Jo Ann Honcik Dallara

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GILBERT and WAKARCHUK

Application No.:

Filed: April 8, 2004

For: SIALYLTRANSFERASES FROM
C. JEJUNI

Customer No. 20350

Examiner:

Art Unit:

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

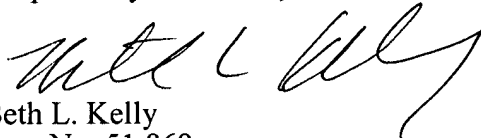
Sir:

The references cited on the attached documents (see list of Enclosures at bottom) are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 10/303,128, filed November 21, 2002 (Attorney Docket No. 019633-000112US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicants believe that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,


Beth L. Kelly
Reg. No. 51,868

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
BLK:jhd

Enclosures: IDS of 11/21/02 w/ PTO/SB/08B citing refs. AA-AX (w/ Examiner initialed copy)
Supplemental IDS of 2/27/03 w/ PTO/SB/08B citing ref. AA (w/ Examiner initialed copy)
PTO-892 (Paper No. 0104) citing refs. U and V

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GILBERT and WAKARCHUK

Application No.:

Filed: Herewith

For: NUCLEIC ACIDS ENCODING
BETA-1,4-GALNAC TRANSFERASE

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, be made of record therein and appear among the "references cited" on any patent to issue therefrom.

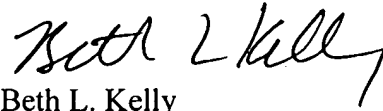
Also enclosed is a copy of the Search/Examination report corresponding to the PCT application.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the

undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Beth L. Kelly". The signature is fluid and cursive, with the first name "Beth" and last name "Kelly" clearly distinguishable.

Beth L. Kelly
Reg. No. 51,868

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
BLK/llc
SF 1404050 v1

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| Applicant's or agent's file reference 40330-1859 | FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. | |
| International application No. PCT/CA 02/ 00229 | International filing date (day/month/year) 22/02/2002 | (Earliest) Priority Date (day/month/year) 21/03/2001 |
| Applicant NATIONAL RESEARCH COUNCIL OF CANADA | | |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.
☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

- ☒ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 02/00229

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N9/10 C12N9/12 C12Q1/68 C12N15/54 C12N5/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, SEQUENCE SEARCH

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|------------------------------------------------------------------------------------------------------------|-----------------------|
| X | WO 00 46379 A (CANADA NAT RES COUNCIL) 10 August 2000 (2000-08-10) the whole document --- -/-- | 1-42 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

8 November 2002

Date of mailing of the international search report

19/11/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Strobel, A

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 02/00229

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | <p>GILBERT M ET AL: "BIOSYNTHESIS OF GANGLIOSIDE MIMICS IN CAMPYLOBACTER JEJUNI OH4384 IDENTIFICATION OF THE GLYCOSYLTRANSFERFERASE GENES, ENZYMATIC SYNTHESIS OF MODEL COMPOUNDS, AND CHARACTERIZATION OF NANOMOLE AMOUNTS BY 600-MHZ 1H AND 13C NMR ALAYSIS" JOURNAL OF BIOLOGICAL CHEMISTRY, AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BALTIMORE, MD, US, vol. 275, no. 6, 11 February 2000 (2000-02-11), pages 3896-3906, XP000893010 ISSN: 0021-9258 the whole document</p> | 1-42 |
| X | <p>WOOD A C ET AL: "CLONING, MUTATION AND DISTRIBUTION OF A PUTATIVE LIPOPOLYSACCHARIDEBIOSYTHESIS LOCUS IN CAMPYLOBACTER JEJUNI" INT. CONF. ON ALGORITHMS & ARCHITECTURES FOR PARALLEL PROCESSING, XX, XX, vol. 145, no. 2, February 1999 (1999-02), pages 379-388, XP000892785 page 382 -page 387, left-hand column, paragraph 2</p> | 1-42 |
| A | <p>PARKHILL J ET AL: "THE GENOME SEQUENCE OF THE FOOD-BORNE PATHOGEN CAMPYLOBACTER JEJUNIREVEALS HYPERVARIABLE SEQUENCES" NATURE, MACMILLAN JOURNALS LTD. LONDON, GB, vol. 403, 10 February 2000 (2000-02-10), pages 665-668, XP000906767 ISSN: 0028-0836 the whole document</p> | 1-42 |
| X | <p>& HTTP://WWW.SANGER.AC.UK/PROJECTS/C_JEJUNI/ ,</p> | 1-42 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 02/00229

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|-------------------------------------------|---|---------------------|----------------------------|---------------------|
| WO 0046379 | A | 10-08-2000 | AU 2274300 A | 25-08-2000 |
| | | | WO 0046379 A1 | 10-08-2000 |
| | | | EP 1147200 A1 | 24-10-2001 |
| | | | US 2002042369 A1 | 11-04-2002 |
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| Substitute for form 1449B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | |
| | | | | Filing Date | |
| | | | | First Named Inventor | |
| | | | | Art Unit | |
| | | | | Examiner Name | |
| (use as many sheets as necessary) | | | | Unassigned | |
| Sheet | 1 | of | 2 | Attorney Docket Number | 019633-000112US |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|-------------------------------------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|
| Examiner | Cite No. ¹ | Document Number Number Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | AA | US-5,352,670 | 10-04-1994 | Venot, et al. | |
| | AB | US-5,374,541 | 12-20-1994 | Wong, et al. | |
| | AC | US-5,545,553 | 08-13-1996 | Gotschlich | |
| | | US- | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|--------------------------|---------------------------|---------------------|-----------------------------------|--------------------------------|-------------------------------------------------------|------------------------------------------------------------------------------------|--------------------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | AD | WO | 92/16640 | | 10-01-1992 | The Scripps Research Institute | | <input type="checkbox"/> |
| | AE | WO | 96/32491 | | 10-17-1996 | Cytel Corp. | | <input type="checkbox"/> |
| | AF | WO | 99/49051 | A1 | 09-30-1999 | National Research Council of Canada | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² | |
| | AG | ASPINALL et al., "Lipopolysaccharides of Campylobacter jejuni Serotype O:19: Structures of Core Oligosaccharide Regions from the Serostrain and Two Bacterial Isolates from Patients with the Guillain-Barré Syndrome" Biochemistry, 33: 241-249 (1994b) | | |
| | AH | ASPINALL et al., "Lipopolysaccharides of Campylobacter jejuni Serotype O:19: Antigen Chains from the Serostrain and Two Bacterial Isolates from Patients with the Guillain-Barré Syndrome" Biochemistry, 33: 250-255 (1994c) | | |
| | AI | ASPINALL, et al. " Chemical Structures of the Core Regions of Campylobacter Jejuni Serotypes 0:1, 0:4, 0:23, and 0:36 Lipopolysaccharides," European Journal of Biochemistry, Vol. 213, No. 3, pp. 1017-1027, (May 1993) | | |
| | AJ | ASPINALL, et al. "Lipopolysaccharides from Campylobacter Jejuni Associated with Guillain-Barré Syndrome Patients Mimic Human Gangliosides in Structure," Infection and Immunity, Vol. 62, No. 5, pp. 2122-2125, (May 1994) | | |
| | AK | BELUNIS et al., "Biosynthesis of Endotoxin" J. Biol. Chem., 267: 9988-9997 (1992) | | |
| | AL | GAUDINO et al., "A Novel and Efficient Synthesis of Neolacto Series Gangliosides 3'-nLM1 and 6'-nLM1 " J. Am. Chem. Soc., 116: 1149-1150 (1994) | | |

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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SF 1404050 v1



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|---------------------------------------------------------------------------------------------------|-------------|--------------------------|--------------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | |
| | | Filing Date | Herewith |
| | | First Named Inventor | Gilbert, Michel, et. al. |
| | | Art Unit | Unassigned |
| | | Examiner Name | Unassigned |
| Sheet 2 | of 2 | Attorney Docket Number | 019633-000112US |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | AM | GILBERT et al., "Cloning of the Lipooligosaccharide α -2,3-Sialyltransferase from the Bacterial Pathogens <i>Neisseria Meningitidis</i> and <i>Neisseria Gonorrhoeae</i> ," Journal of Biological Chemistry, Vol. 271, No. 45, pp. 28271-28276, The American Society for Biochemistry and Molecular Biology, Inc., USA, (November 8, 1996) | |
| | AN | GILBERT, et al., "Biosynthesis of Ganglioside Mimics in <i>Campylobacter Jejuni</i> OH4384," The Journal of Biological Chemistry, Vol. 275, No. 6, pp. 3896-3906, The American Society for Biochemistry and Molecular Biology, Inc., USA, (February 11, 2000) | |
| | AO | ITO et al., "Synthesis of Bioactive Sialosides" Pure Appl. Chem., 65: 753 (1993) | |
| | AP | KUROKI, "Campylobacter jejuni Strains from Patients with Guillain-Barré Syndrome Belong Mostly to Penner Serogroup 19 Contain β -N-Acetylglucosamine Residues" Ann. Neurol., 33: 243-247 (1993) | |
| | AQ | PARKHILL, et al. "The Genome Sequence of the Food-Borne Pathogen <i>Campylobacter Jejuni</i> Reveals Hypervariable Sequences," Nature, Vol. 403, pp. 665-668, (February 10, 2000) | |
| | AR | PENNER, et al., "Diversity of Lipopolysaccharide Structures in <i>Campylobacter Jejuni</i> ," The Journal of Infectious Diseases, Vol. 176, No. 2, pp. S135-S138, (December 1997) | |
| | AS | PRENDERGAST, et al., "Lipopolysaccharides from <i>Campylobacter Jejuni</i> O:41 Strains Associated with Guillain-Barré Syndrome Exhibit Mimicry of GM1 Ganglioside," Infection and Immunity, Vol. 66, No. 8, pp. 3649-3677, (August 1998) | |
| | AT | PRESTON, et al., "The Lipooligosaccharides of Pathogenic Gram-Negative Bacteria," Critical Reviews in Microbiology, Vol. 22, No. 3, pp. 139-180, (1996) | |
| | AU | SABESAN et al., "Combined Chemical and Enzymatic Synthesis of Sialyloligosaccharides and Characterization by 500-MHz ¹ H and C NMR Spectroscopy" J. Am. Chem. Soc., 108: 2068-2080 (1986) | |
| | AV | SALLOWAY, et al., "Miller-Fisher Syndrome Associated with <i>Campylobacter Jejuni</i> Bearing Lipopolysaccharide Molecules that Mimic Human Ganglioside GD3," Infection and Immunity, Vol. 64, No. 8, pp. 2945-2949, (August 1996) | |
| | AW | WAKARCHUK et al., "Functional Relationships of the Genetic Locus Encoding the Glycosyltransferase Enzymes Involved in Expression of the Lacto-N-neotetraose Terminal Lipopolysaccharide Structure in <i>Neisseria meningitidis</i> " J. Biol. Chem., 271: 19166-19173 (1996) | |
| | AX | WOOD, et al., "Cloning, Mutation and Distribution of a Putative Lipopolysaccharide Biosynthesis Locus in <i>Campylobacter Jejuni</i> ," Microbiology, Vol. 145, No. 2, pp. 379-388, (February 1999) | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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PATENT
Attorney Docket No.: 019633-000112US
Client Reference No.: 10983-1A

Assistant Commissioner for Patents
Washington, D.C. 20231

On 2/27/03

TOWNSEND and TOWNSEND and CREW LLP

By: London Clark

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GILBERT and WAKARCHUK

Application No.: 10/303,128

Filed: November 21, 2002

For: NUCLEIC ACIDS ENCODING
BETA-1,4-GALNAC TRANSFERASE

Examiner: Unassigned

Art Unit: 1652

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER 37
CFR §1.97 and §1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Also enclosed is a copy of the Search/Examination report corresponding to the PCT application.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Beth L. Kelly
Reg. No. 51,868

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
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SF 1436766 v1

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|-------------------------------|--------------------------|
| Application Number | 10/303,128 |
| Filing Date | November 21, 2002 |
| First Named Inventor | Gilbert, Michel, et. al. |
| Art Unit | 1652 |
| Examiner Name | Unassigned |
| Attorney Docket Number | 019633-000112US |

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|-------|---|----|---|
| Sheet | 1 | of | 1 |
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[illegible]Date
Considered

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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| | | | |
|-----------------------------------|---------------------------------------|--------------------------------------------------------------|-------------|
| Notice of References Cited | Application/Control No. 10/303,128 | Applicant(s)/Patent Under Reexamination GILBERT ET AL. | |
| | Examiner Sheridan L. Swope | Art Unit 1652 | Page 1 of 1 |

U.S. PATENT DOCUMENTS

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|---|--------------------------------------------------|-----------------|------|----------------|
| | A | US- | | | |
| | B | US- | | | |
| | C | US- | | | |
| | D | US- | | | |
| | E | US- | | | |
| | F | US- | | | |
| | G | US- | | | |
| | H | US- | | | |
| | I | US- | | | |
| | J | US- | | | |
| | K | US- | | | |
| | L | US- | | | |
| | M | US- | | | |

FOREIGN PATENT DOCUMENTS

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Country | Name | Classification |
|---|---|--------------------------------------------------|-----------------|---------|------|----------------|
| | N | | | | | |
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NON-PATENT DOCUMENTS

| * | | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|-------------------------------------------------------------------------------------------------------------------------------------------|
| | U | Ausubel et al Protein Expression In: Current Protocols in Molecular Biology Wiley and Sons, Inc. 1987 Chapter 16. |
| | V | Tomb et al The complete genome sequence of the gastric pathogen Helicobacter pylori. Swiss-Prot Acc#A64547. Alignment with SEQ ID NO: 17. |
| | W | |
| | X | |

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.